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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,425	07/03/2001	Roberto Valducci	242/9-1568	1890

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,425

Applicant(s)

ROBERTO VALDUCCI

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges receipt of amendment filed 01/16/04. Examiner further acknowledges receipt of English language translation of the foreign priority document, MI2000A001603. Claims 35-46 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirakawa et al. (US 5,725,880) in view of Khan et al. ("A pH-dependent colon targeted oral delivery system using methacrylic acid copolymers I. Manipulation of drug release using EUDRAGIT L100-55 and EUDRAGIT S100 combinations, J. of Controlled Release, 58, (1999) pp 215-222).

Hirakawa discloses a pharmaceutical formulation that is controlled to release medicine at a targeted site in the gastrointestinal tract (abstract and column 1, lines 8-14); the control process involves coating the core of the formulation with pH-dependent enteric polymers such as the EUDRAGIT L and S methacrylic/methyl methacrylic polymers (column 4, lines 45-62); and granules of 5-Aminosalicylic acid or mesalazine are coated (examples 3-5).

Hirakawa discloses coating the granules of 5-Aminosalicylic acid or mesalazine with EUDRAGIT L and S methacrylic/methyl methacrylic polymers in order to deliver the medicine to targeted site in the gastrointestinal tract. However, Hirakawa coats the granular formulation with a specific combination of the EUDRAGIT for delivery at a specific site and does not divide

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the granular formulation for coating with specific EUDRAGIT to ensure delivery at different specific sections of the GI depending on the pH of the EUDRAGIT. But Khan discloses using EUDRAGIT combinations to control the delivery of mesalazine at pHs of 5.5 to 7.0 (J. of Controlled Release, 58, (1999) pp 215-222). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat granular formulation of mesalazine with EUDRAGIT polymers to control the delivery of the medicine to specific site of the GI. One having ordinary skill in the art would have been motivated optimize the controlled delivery of the medicine by coating separate portions of the granules with designated EUGRAGIT or combinations of EUDRAGIT with the expectation of delivering the medicine at different pH's along the GI.

Observation: The invention appears to be directed to a particulate formulation where the particles or granules are divided into three portions; one portion is coated with specific EUDRAGIT for release at say pH 6, the second portion is coated with specific EUDRGIT for release at 6.5 and the third is coated with specific EUDRAGIT for release at pH 7 (instant claims 43-46). However, the generic claim 35 does not specifically reflect the invention as stated in this observation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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